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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/862,710 | 05/23/2001 | Chirag B. Shah | P296 DIV1 | 1806 |

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| EXAMINER |
|---|
| ROBERTSON, JEFFREY |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1712 | 4 |

DATE MAILED: 07/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

MF=4

| Offic Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/862,710 | SHAH ET AL. | |
| | Examiner | Art Unit | |
| | Jeffrey B. Robertson | 1712 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 May 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Priority*

1. The disclosure is objected to because of the following informalities: The status of the parent application should be updated on page 1, line 3 of the specification.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for biopolymers selected from heparin-tridodecylmethylammonium chloride and other heparin complexes, does not reasonably provide enablement for biopolymers derived from heparin-tridodecylmethylammonium chloride and other heparin complexes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification, in paragraphs [0027] and [0029], on pages 6 and 7, sets forth that the biopolymer may be heparin-tridodecylmethylammonium chloride and other heparin complexes. The

specification provides no direction on what derivatives of these complexes may be used, how they are prepared or what structure they may have.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For claim 9, there is a lack of antecedent basis for the term "the heparin" since no such term has been previously set forth in any of claims 1, 7, or 9.

### *Claim Rejections - 35 USC § 102*

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

7. Claims 1 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Dyck (U.S. Patent No. 3,639,141).

For claims 1 and 10, in column 1, lines 15-20, Dyck teaches that heparin (biopolymer) is bonded to the surface of a plastic in order to render the surface nonthrombogenic. In column 1, lines 28-35, Dyck teaches that the heparin is bound to the surface of the plastic through an amino alkyl alkoxy silane. For claim 1, in column 2, lines 65-69, Dyck teaches that the amino groups of the silane readily bond with heparin. Thus the coating on the surface contains a biopolymer covalently bound to a silane.

8. Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagata et al. (U.S. Patent No. 4,082,727).

For claim 1, in column 1, line 48 through column 2, line 7, Nagata teaches that an organosilicon compound (silane) is reacted with a heparin salt (biopolymer) to form an organosilicon compound with a heparin linkage, i.e. a covalent bond between the silane and the biopolymer (see also column 2, line 17). For claims 1 and 10 in column 5, lines 36-40, Nagata teaches that this material can be used as a coating, particularly for medical devices to impart an anticoagulant (thromboresistant) property to the medical device.

For claims 2-4, and 7, in column 2, lines 43-51, Nagata teaches organosilicon compounds that contain an isocyanate group, which will react with a hydroxyl group as set forth by Nagata in column 3, lines 6-13. For claim 13, all of the organosilicon compounds listed by Nagata have a propyl group between the isocyanate functionality and the silane.

For claims 5, 6, 8, and 11, in column 1, lines 58-63, Nagata teaches that the heparin compound is a salt formed between heparin and tridodecylmethylammonium chloride.

For claim 9, in column 1, lines 58-67, Nagata teaches that the heparin complexes are soluble in organic solvents.

For claim 12, Nagata teaches an additive in the form of a RTV silicone rubber that is added to the heparin-silane product in column 7, lines 4-9.

9. Claims 1 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Morra et al. (WO 96/24392).

For claim 1, on page 9, lines 9-14, Morra teaches a coating of hyaluronic acid for biomedical objects. On page 12, lines 24-34, Morra discloses that the hyaluronic acid is reacted with an alkoxy silane coupling agent. In the paragraph bridging pages 12 and 13, Morra teaches that a reaction product of hyaluronic acid and the silane is formed, indicating the presence of a covalent bond. On page 1, lines 20-22, Morra describes that hyaluronic acid is a biopolymer in that it occurs naturally in practically all tissues.

For claim 12, on page 14, lines 7-30, Morra teaches additives such as condensing agents that may be added to the process.

10. Claims 1, 2, 7, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Baney et al. (EP 0 581 576).

For claims 1 and 7, on page 2, lines 1-3, Baney teaches the reaction of an organic polymer containing a hydroxyl group with an alkoxysilane. On page 4, line 3, Baney discloses that the polymer is a hydroxyl-functional polysaccharide. On page 5,

lines 33-34, Baney teaches that the modified polymers may be used as protective coatings and biocompatible materials.

For claim 2, Baney discloses in column 2, lines 42-48 that the alkoxide on the silicon atom reacts with the hydroxyl group on the polymer.

For claim 12, on page 4, lines 11-16, Baney teaches the addition of an additive in the form of a catalyst.

11. Claims 1, 10, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Rowland et al. (U.S. Patent No. 5,356,433).

For claim 1, in column 5, lines 22-47, Rowland teaches that biologically active agents are covalently linked to an organosilane on a surface of a metal. For claims 1 and 10, in column 5, lines 48-51, Rowland specifically mentions anti-thrombogenic agents such as heparin. Therefore, the coating contains a biopolymer that is covalently linked to a silane.

For claim 12, Rowland teaches the addition of an additive in the form of a coupling agent in column 5, lines 27-31.

12. Claims 1, 2, 7, 8, 10, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Tsang et al. (U.S. Patent No. 5,955,588).

For claim 1, in column 3, lines 50-55, Tsang teaches a coating composition that contains a silyl group covalently bonded to heparin. In column 5, lines 44-57, Tsang specifically teaches situations where n=1, indicating that a silane is present. For claims 2 and 7, in column 4, lines 38-47, Tsang teaches that the silyl group is covalently linked through a hydroxyl group present on the heparin molecule.

For claim 8, in column 3, lines 57-67, Tsang teaches that heparin adducts such as benzalkonium heparin may be used.

For claim 10, in column 3, lines 5-7, Tsang teaches that the coatings have non-thrombogenic properties.

For claim 12, in column 7, lines 59-65, Tsang teaches that an additive may be added to the coating composition.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey B. Robertson whose telephone number is (703) 306-5929. The examiner can normally be reached on Mon-Fri 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Dawson can be reached on (703) 308-2340. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Jeffrey B. Robertson
Patent Examiner
A.U. 1712
July 9, 2002